

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 16 JAN 2007

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Applicant's or agent's file reference 1059.00122	<b>FOR FURTHER ACTION</b>		See Form PCT/IPEA/416
International application No. PCT/US04/33049	International filing date (day/month/year) 07 October 2004 (07.10.2004)	Priority date (day/month/year) 07 October 2003 (07.10.2003)	
International Patent Classification (IPC) or national classification and IPC IPC: A61B 17/22( 2007.01),17/32( 2007.01) USPC: 606/159,170			
Applicant HENRY FORD HEALTH SYSTEM			

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

a. ☒ (sent to the applicant and to the International Bureau) a total of 3 sheets, as follows:

☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) \_\_\_\_\_, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- ☒ Box No. I Basis of the report
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand

04 May 2005 (04.05.2005)

Date of completion of this report

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Form PCT/IPEA/409 (cover sheet)(April 2005)

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US04/33049

**Box No. I Basis of the report**1. With regard to the **language**, this report is based on:

- ☐ the international application in the language in which it was filed.
- ☐ a translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
- ☐ publication of the international application (under Rule 12.4(a))
- ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

- ☐ the international application as originally filed/furnished
- ☒ the description:  
pages 1-10 as originally filed/furnished  
pages\* NONE received by this Authority on \_\_\_\_\_  
pages\* NONE received by this Authority on \_\_\_\_\_
- ☒ the claims:  
pages 11-13 as originally filed/furnished  
pages\* NONE as amended (together with any statement) under Article 19  
pages\* NONE received by this Authority on \_\_\_\_\_  
pages\* NONE received by this Authority on \_\_\_\_\_
- ☒ the drawings:  
pages NONE as originally filed/furnished  
pages\* 1/3-3/3 received by this Authority on 05 April 2005 (05.04.2005)  
pages\* NONE received by this Authority on \_\_\_\_\_
- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.  
PCT/US04/33049**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims <u>9,10,17</u>	YES
	Claims <u>1-8, 11-16, 18, 19</u>	NO
Inventive Step (IS)	Claims <u>17</u>	YES
	Claims <u>1-16, 18-19</u>	NO
Industrial Applicability (IA)	Claims <u>1-19</u>	YES
	Claims <u>NONE</u>	NO

**2. Citations and Explanations (Rule 70.7)**

Claims 1-8 lack novelty under PCT Article 33(2) as being anticipated by US 5,156,610 to Reger.

(claim 1) Reger teaches an embolectomy catheter 10 comprising a lumen including a grooved insertion end 32.

(claim 2) Reger teaches a grooved tip 18 attached to the insertion end.

(claim 3) Reger teaches a fixed tip (Fig. 1).

(claim 4) Reger teaches a rotating tip (from Fig. 2 to Fig. 3).

(claim 5) Reger teaches the grooved tip affixed via a coupling joint (Fig. 1).

(claim 6) Reger teaches the groove end including a spiral groove (Fig. 1-3).

(claim 7) Reger teaches perfusion sideholes 94.

(claim 8) Reger teaches a plunger 14.

Claims 9 and 10 lack an inventive step under PCT Article 33(3) as being obvious over US 5,156,610 to Reger in view of US 5,700,269 to Pinchuk et al.

Reger is silent with regards to the device formed from a hydrophilic material, such as hydrogel. Pinchuk teaches a catheter comprising a plunger that is made of hydrogel (col. 5, line 21). Therefore, it would have been obvious to one of ordinary skill in the art to form the device of Reger with hydrogel, since it is well known in the art to use Hydrogel to form a part of a catheter/plunger device, as taught by Pinchuk.

Claims 11-16, 18 and 19 lack novelty under PCT Article 33(2) as being anticipated by US 6,022,363 to Walker et al.

(claim 11) Walker teaches a method of treating a thrombus by inserting a catheter and rotating the catheter within the individual, thereby breaking the thrombus (col. 13, line 14 - col. 14, line 34).

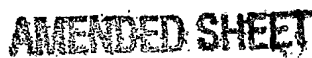
(claim 12) Walker teaches rotating the catheter to break the thrombus.

(claim 13) Walker teaches the step of removing the broken fragments (dissolves).

(claims 14-16, 18 and 19) Walker teaches administering thrombolytic agents and preventing distal migration of fragments (col. 14, lines 1-10).

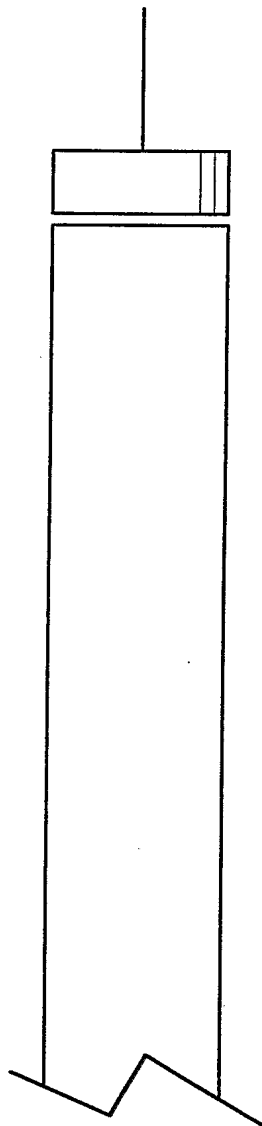
Claim 17 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a method of treating a thrombus comprising, among other features, preventing the migration of the fragments by inserting a plunger.

Claims 1-19 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

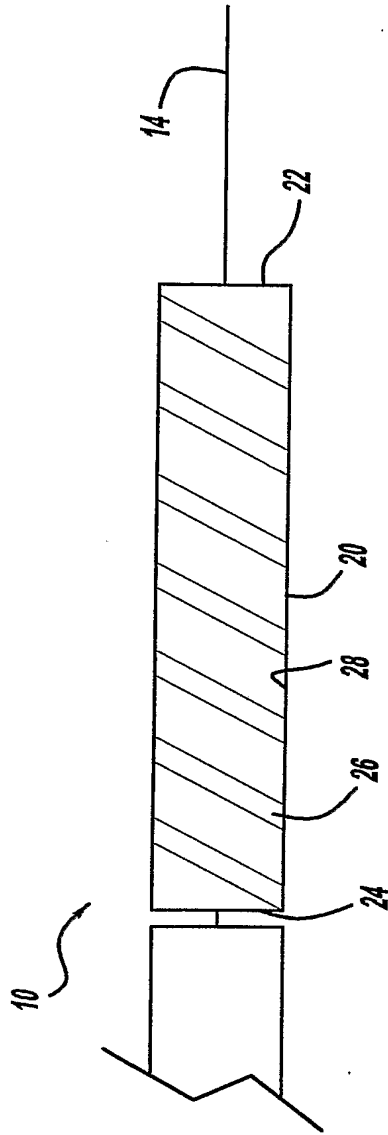


MEANS

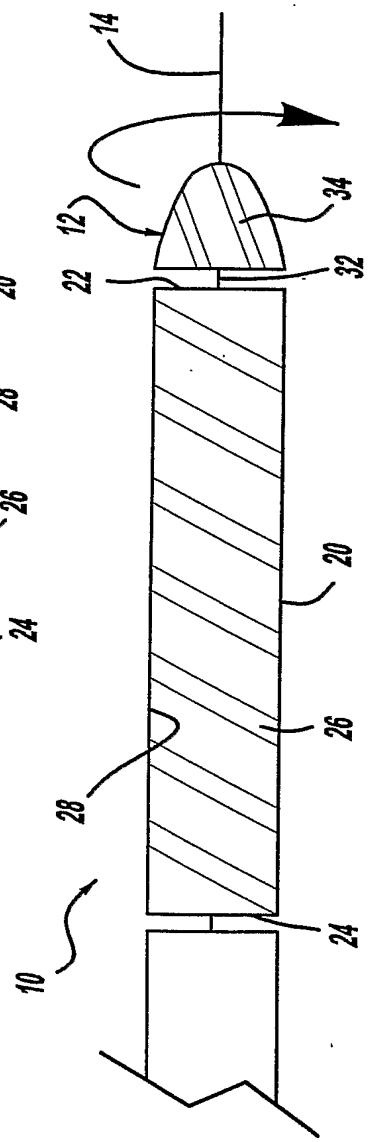
**FIG - 2A**



**FIG - 2B**

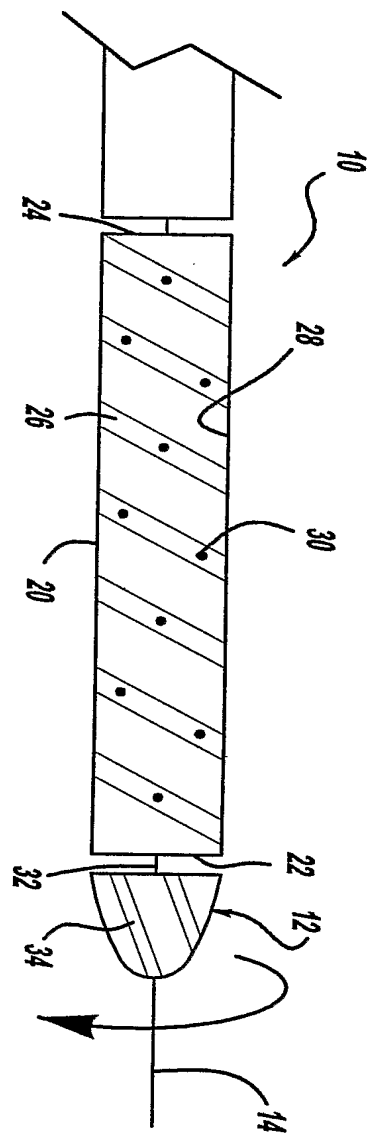


**FIG - 2C**

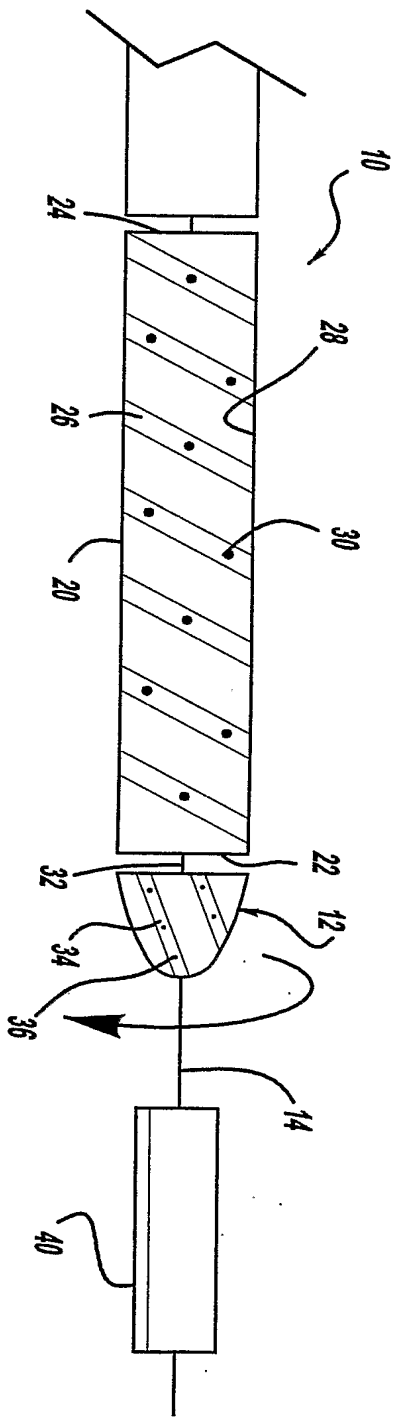


AMENDED SHEET

12/14/12



**FIG - 2D**



**FIG - 2E**